DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-597/S-014

Pharmacia & Upjohn Corporation
Attention: Gregory G. Shawaryn
Regulatory Affairs Manager
7000 Portage Road
Kalamazoo, Michigan 49001

Dear Mr. Shawaryn:

Please refer to your supplemental new drug application dated January 21, 2000, received January 24, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xalatan (latanoprost ophthalmic solution) 0.005% (50 μg/mL).

We acknowledge receipt of your submissions dated May 30, July 17 and 19, and November 17, 2000. Your submission of November 17, 2000, constituted a complete response to our May 16, 2000, action letter.

This "Changes Being Effected" supplemental new drug application provides for revised labeling of the package insert to add corneal edema and erosions, herpes keratitis, and keratitis to the Clinical Practice subsection of the Adverse Reactions section. The revised paragraph will read as follows:

> **Clinical Practice:** The following events have been identified during postmarketing use of XALATAN in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to XALATAN, or a combination of these factors, include: asthma and exacerbation of asthma; corneal edema and erosions; dyspnea; eyelash changes (increased length, thickness, pigmentation, and number of lashes); eyelid skin darkening; herpes keratitis; intraocular inflammation (iritis/uveitis); keratitis; macular edema, including cystoid macular edema; and toxic epidermal necrolysis.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the electronic submission of final printed labeling of the package insert submitted November 17, 2000. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research